Independent claims 1, 28 and 29 disclose an apparatus for effecting a change in at least a portion of the selected site of collagen containing tissue that is adjacent to a fluid medium. Claims 1, 28 and 29 are amended to specify the apparatus as having a coaxial distal portion with a blunt periphery guidable and positionable in contact with a surface of the selected site without penetrating the surface of the selected site. The coaxial distal portion allows the apparatus to be guided and positioned at the selected site for delivery of energy to contact and treat collagen containing tissue adjacent to a fluid medium without the use of a separate probe that must be separately positioned and then separately deployed.

In contrast, Edwards et al., teaches a medical probe device comprising a catheter having a stylet guide housing with one or more stylet ports in a side wall thereof and guide means for directing a flexible stylet outward (off-axis) through the stylet port and through to the treatment tissue. The catheter is guided to a treatment site by a stylet guide such as directing catheter through the urethra into the prostate (column 6, lines 53-54). The separate guide facilitates the positioning of the stylet for treatment (column 6, lines 59-60) and the separate stylet probe extends out off-axis from the stylet guide to penetrate a target tissue for treatment (column 7, lines 1-4). As a result, Edward does not teach a coaxial distal portion configured to guide the apparatus to the selected site and position the distal portion at the selected site to deliver sufficient energy for treatment.

Further, Makower discloses catheter device for energy delivery having a distal tip and end with a separate needle director channel. The treatment needle extends off-axis from a periphery of the distal tip to the treatment tissue (page 7, lines 11-17). As a result, Makower also does not teach a coaxial distal portion for both guiding and positioning of the energy delivery device at the selected site for treatment as in the present invention.

Moreover, there is nothing in Ishihara to suggest a combination with either Edwards et al., or Makower to teach an energy delivery device with a coaxial distal portion to both guide and position the distal portion for treatment at a selected site. Ishihara discloses a separate distal end portion which is brought to the body wall treatment site (column 3, lines 56) and a separate probe for treatment of the affected part is introduced into a body cavity through a separate, off-axis side instrument channel (column 4, lines 9-12). Thus, there is nothing to suggest a coaxial distal portion of an energy delivery device for treatment as in the present invention.

Neither Edwards et al., nor Makower in combination with Ishihara teach an apparatus with a coaxial distal portion having a blunt periphery guidable and positionable in contact with a surface of the selected site without penetrating the surface of the selected site. Therefore, the rejection under 35 USC §103(a) should be withdrawn.

In addition, each of the independent claims requires a sensor to detect thermal energy from both the selected site and from the fluid medium, thereby producing a thermal feedback signal which represents a composite of the thermal energy detected from the selected site and the fluid medium. None of the references cited by the examiner discloses such a feature. Moreover, such a composite temperature sensor is not "notorious through the art", notwithstanding the examiner's allegations to the contrary. Applicant insists that the Examiner cite a specific reference that clearly describes such a composite temperature sensor.

The composite signal sensor provides a number of specific advantages as discussed in the application as originally filed. For instance, referring to the paragraph bridging pages 17-18, it is possible to design the distal portion of the apparatus such that the signal represents the thermal energy content of specific surfaces or mediums. Further, the sensor can provide a composite signal

of thermal energy and temperature whether or not the fluid medium is flowing or non-flowing. Furthermore, positioning the sensor to provide a composite signal helps to reduce cell narcosis or over-contraction caused by a second application of energy. See page 18, lines 23-25. Furtherstill, referring to page 20, lines 3-16, the composite signal generating sensor will provide a different signal when it is moved toward a previously heated path compared to when it is not traveling to a previously heated path. Significantly, this permits the temperature across the selected area to approach uniformity. Uniformity of temperature is desirable as it reduces cell narcosis or over-contractions near path intersections. See page 20, lines 13-16.

Accordingly, withdrawal of this rejection is respectfully requested.

Claims 1-29 are rejected under the judicially created doctrine of double patenting over claims 1-22 of U.S. Patent No. 5,458,596. The applicant submits a terminal disclaimer to obviate the double patenting rejection over prior U.S. Patent No. 5,458,596.

Accordingly, withdrawal of this rejection is respectfully requested.

An extension of time of three months for a small entity ($465) is requested to respond to the Official Action dated April 2, 1999, thus extending the time for reply to October 2, 1999. Please charge $435 to Deposit Account No. 23-2415 (Docket No. 17616-705).

The Commissioner is hereby authorized to charge payment of any deficiency or credit any overpayment to Deposit Account No. 23-2415.

Respectfully submitted,

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